

REMARKS

Responsive to the Office Action dated June 26, 2003, Applicant hereby makes the following response. The present application was filed on June 8, 2000 and included Claims 1-32. In response to a restriction requirement dated October 9, 2001, Claims 19-26 were restricted out, without prejudice, for a later divisional application, if necessary. A simultaneous election of species resulted in Claims 5-9, 13-18, and 27-32 being withdrawn. New claims 33-48 were added by amendment dated August 2, 2002. Claims 41-47 were also withdrawn by the Examiner as drawn to a nonelected invention and species. In response to the Examiner's suggestions during a personal interview, a Request for Continued Examination and amendment were filed on May 12, 2003. In that amendment, claims 1-4, 10-12, 33-40 and 48 were cancelled and new claims 49-64 were added. Accordingly, Claims 49-64 remain pending with Claim 49 being independent.

I. Summary of the Claims

The present invention is directed to a bio-absorbable and bio-compatible implant for placement under the skin of an animal. The implant includes at least one discrete, solid pellet having from about 5-400 mg of a growth promoting agent wherein the growth promoting agent is selected from the group consisting of trenbolone acetate, estradiol, estradiol benzoate, and combinations thereof. The implant also includes at least one discrete, solid pellet having from about 5-1500 mg of a supplemental agent wherein the supplemental agent is selected from the group consisting of tylosin, tylosin tartrate, melengesterol acetate, and combinations thereof. The growth promoting and supplemental agents combine to promote enhanced growth in an animal.

II. Withdrawal of Claims 52, 55, 59 and 63

The Examiner indicated that Claims 5-9, 13-32, 41-47, 52, 55, 59 and 63 stand as withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. The Examiner also noted that Applicant timely traversed the restriction (election) requirement in Paper No. 16. However, Applicant respectfully submits that Claims 52, 55, 59 and 63 have not been withdrawn and have not been the subject of a restriction or election requirement. These claims were added in the last amendment dated May 12, 2003 are not drawn to nonelected species. Applicant therefore respectfully submits that these claims are not withdrawn and are therefore still pending in the present application.

III. The § 112 Rejections

Claims 49-51, 53, 54, 56-58, 60-62, and 64 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter which applicant regards as the invention. In particular, the term "implant" as used in the preamble of Applicant's claims was objected to as referring to a single device comprising at least 2 discrete pellets. The objection was based upon the assertion that the two separate pellets could be considered as individual implants separated not only in space, but also in time. Applicant respectfully submits, however, that the commonly understood meaning of the term "implant" encompasses more than one pellet. Merriam-Webster's Collegiate Dictionary (10th ed.) defines implant as follows: "2: to insert in a living site (as for growth, slow release, or formation of an organic union)[subcutaneously ~ed hormone pellets]." Applicant therefore submits that the term "implant" is definite and respectfully requests withdrawal of this rejection.

IV. The § 103(a) Rejection

Claims 49-51, 54, 58, 61, 62 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson et al '98 in view of U.S. Patent No. 4,670,249 to Ivy et al. and International Publication No. WO 00/25743 to Shih et al.. For the following reasons, Applicant respectfully submits that the present invention is not obvious under 35 U.S.C. § 103(a) and requests reconsideration and withdrawal of this rejection.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Johnson does not teach or suggest the claimed invention. As stated in the Office Action, Johnson teaches enhanced lamb growth using an implant containing two growth promotants, namely, trenbolone acetate and estradiol. There is no teaching or suggestion of an implant including *both* a growth promoting agent *and* a supplemental agent. Moreover, the Office Action confirms that Johnson also does not teach an implant having two separate pellets.

Ivy also does not teach or suggest the present invention. Like Johnson, Ivy merely discloses the use of two different growth promotants, namely, a growth hormone and a zearalin. There is no teaching or suggestion by Ivy to provide an implant having *both* a growth promoting agent and a supplemental agent.

Similarly, Shih does not teach or suggest the present invention. Shih only discloses the administration of immediate-release and controlled-release formulations of zearalins. As discussed above in connection with the Ivy reference, zearalins are growth promotants *not* supplemental agents. Thus, there is no disclosure in Shih of the combination of a growth promoting agent and a supplemental agent.

Finally, prima facie obviousness requires that there must be a reasonable expectation of success when prior art is modified or combined. In the present application, there is no reasonable expectation of success in achieving the invention as claimed when the cited references are modified or combined. As discussed above, none of the cited references contain all the elements of Applicants' independent claim. Unless all the elements are taught by the references, there can be no success in modifying them.

Thus, at the time the present invention was made, Johnson, Ivy and Shih fail to teach or describe *all* of the limitations claimed by Applicant in its independent claim and the claims depending therefrom. Accordingly, independent claim 49 and the claims depending therefrom are nonobvious under § 103 (a).

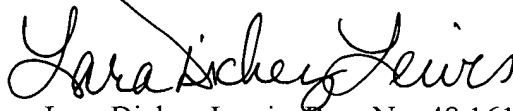
V. Conclusion

Applicant respectfully requests withdrawal of the rejections and believes that the claims as presented represent allowable subject matter. However, if the Examiner desires, the applicant is ready for a telephone interview to expedite prosecution. As always, the Examiner is free to call the undersigned at 816.460.2516. Should any fees be necessitated by this response, the Commissioner is hereby authorized to deduct any such fees from Deposit Account No. 19-3140.

Respectfully submitted,

SONNENSCHN NATH & ROSENTHAL LLP

By

A handwritten signature in black ink, reading "Lara Dickey Lewis". The signature is written in a cursive, flowing style with a large initial "L".

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